NOV 2 9 2001

510(k) Summary

Drystar 4500M

K012941

Common/Classification Name: Medical Image Hard Copy Device
21 CFR 892.2040

Agfa Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Jeff Jedlicka, Prepared: August 30, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

On April 27, 2001, FDA cleared the Drystar 4500 printer under 510(k) number K010275. The **Drystar 4500M**, the subject of the present 510(k), is very similar to the currently marketed Drystar 4500 in both hardware and software. From the point of view of the hardware and software, the **Drystar 4500M** is substantially equivalent to the Drystar 4500. From the point of view of the intended use of the device, the printing of mammography images, the device is substantially equivalent to the Kodak Dryview 8610 Laser Imager for Mammography, which was cleared by FDA on 27 September 2000 as K002146. The Dryview 8610 also has a similar dry process thermal imaging technology to that of the **Drystar 4500M**.

B. DEVICE DESCRIPTION

The Drystar 4500M is a dry, B/W printer, using the direct thermal printing principle to establish continuous-tone images with medical diagnostic image quality. The printer can be sold with one or two film input trays; one can contain 8 x 10 film and the other 10 x 12 film. Film may be loaded in full daylight. The printer is a network-only printer.

The Drystar 4500M uses a thicker film for mammography than is used for regular medical images in order to provide a wider range of optical densities. The printer also handles borders for mammography images in a different manner than for regular medical images. Otherwise, the device is very similar to the Drystar 4500.

C. INTENDED USE

The **Drystar 4500M** is a free-standing printer used to print diagnostic images on transparent film for viewing on a standard view box. It may be used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable, including digital mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Drystar 4500M** is a medical device and it has the same indications for use as the legally marketed Drystar 4500, except specific reference to mammography is added, as in the indications for use for the Kodak 8610 Dryview Printer. The **Drystar 4500M** has the identical technological characteristics as the Drystar 4500, and these are similar to those of the Kodak 8610. This premarket notification has described the characteristics of the **Drystar 4500M** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the **Drystar 4500M** are identical to those of the predicate device, the Drystar 4500. The technological characteristics of the **Drystar 4500M** are also very similar to those of the Kodak 8610, another dry process printer.

F. TESTING

The device was tested for electrical safety according to EN 60601-1-1 and UL-2601, as described in the 510(k) for the Drystar 4500. The electrical systems are the same across the different models of the Drystar family of printers.

The device was tested for electromagnetic compatibility according to EN 60601-1-2, as described in the 510(k) for the Drystar 4500. The electrical systems and chassis are the same across the models of the Drystar family of printers.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(I)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2001

Agfa Corporation
% T. Whit Athey, Ph.D.
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ROCKVILLE MD 20852

Re: K012941
Trade/Device Name: Drystar 4500M Printer
Digital Image Hardcopy Device
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: August 30, 2001
Received: August 31, 2001

Dear Dr. Whit Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K012941

Device Name: Drystar 4500M

Indications For Use:

The **Drystar 4500M** is a free-standing printer used to print diagnostic images on transparent film for viewing on a standard view box. It may be used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable, including digital mammography.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012941

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)